K101468

APR 14 2011

Premarket Notification 510(k) Summary

Sponsor Information:	3M Health Care 3M Center, Bldg. 275-5W-06 St. Paul, MN 55144-1000
Primary Contact Person:	Linda Johnsen Regulatory Affairs Specialist Phone Number: (651) 737-4376 FAX Number: (651) 737-5320
Date of Summary:	October 6, 2010
Device Common Name:	Sterile Disposable Surgical Gowns
Proprietary Name:	3M™ Basic Disposable Surgical Gown (REF 7492, 7493 & 7494) 3M™ HP Disposable Surgical Gown (REF 7691C, 7692C, 7693C & 7694C) 3M™ Reinforced Disposable Surgical Gown (REF 7595C, 7596C, 7597C & 7598C) 3M™ Disposable Surgical Gown (REF 7591C, 7592C, 7593C, & 7594C) 3M™ HP Reinforced Disposable Surgical Gown (REF 7695C, 7696C, 7697C, & 7698C)
Classification Name:	Surgical Apparel (Class II, 21 CFR § 878.4040)
Product Code:	FYA
Performance Standards:	None
Predicate Device:	Kimberly Clark, Ultra Film-Reinforced Surgical Gown (K080795)

Intended Use:
The 3M™ Basic Disposable Surgical Gowns, 3M™ Disposable Surgical Gowns and 3M™ HP Disposable Surgical Gowns are items of surgical apparel intended to be worn by health care professionals to help protect both the patient and health care worker from transfer of microorganisms, body fluids and particulate matter. These gowns meet level 2 of the AAMI Liquid Barrier Classification.

The 3M™ Reinforced Disposable Surgical Gowns and 3M™ HP Reinforced Disposable Surgical Gowns are items of surgical apparel intended to be worn by health care professionals to help protect both the patient and health care worker from transfer of microorganisms, body fluids and particulate matter. The extra reinforced material is non-permeable and therefore provides a 100% barrier to liquids and blood. These gowns meet level 4 of the AAMI Liquid Barrier Classification within the critical areas of the gowns.*

*To fulfill these requirements, extra reinforced material sheets are integrated into parts of the gown on the front panel and in both sleeves from the cuff to the elbow.

These gowns are for single use.

Description of Device:
The 3M surgical gowns are sterile, disposable and intended for single use. They come in a variety of sizes (M, L, XL and XXL). Their construction includes a blue nonwoven fabric consisting of either a SMMS or Spunlace. Those gowns that are labeled reinforce include extra reinforced material sheets integrated into parts of the gown within the front panel and on both sleeves from the cuff to the elbow. The gowns include a specific AAMI Liquid Barrier Performance and Classification (i.e. 2 or 4) Level. All gowns are easy to don and include a hook and loop to close the neck and ties for closing the back of the gown. They include functional cuffs constructed of a white knitted material.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Element	3M Basic Disposable Surgical Gown Cat # s 7492 7493 7494	3M Disposable Surgical Gown Cat # s 7591C 7592C 7593C 7594C	3M Reinforced Disposable Surgical Gown Cat # s 7595C 7596C 7597C 7598C	3M HP Disposable Surgical Gown Cat# s 7691C 7692C 7693C 7694C	3M HP Reinforced Disposable Surgical Gown Cat# s 7695C 7696C 7697C 7698C	K080795 KC Ultra Film Reinforce Surgical Gown
Intended Use	Same	Same	Same	Same	Same	Same
Sterile	Yes	Yes	Yes	Yes	Yes	Yes
Single Use	Yes	Yes	Yes	Yes	Yes	Yes
Disposable	Yes	Yes	Yes	Yes	Yes	Yes
AAMI Fluid Barrier Protection Level	Level 2	Level 2	Level 4	Level 2	Level 4	Level 4
Flammability Level	Class 1	Class 1	Class 1	Class 1	Class 1	Class 1
Materials	Nonwoven SMMS	Nonwoven Spunlace	Nonwoven Spunlace	Nonwoven SMMS	Nonwoven SMMS	Nonwoven SMS
Optional Sizes (i.e. L)	Yes	Yes	Yes	Yes	Yes	Yes
hook-and-loop neck closure	Yes	Yes	Yes	Yes	Yes	Yes
Tie waist closure	Yes	Yes	Yes	Yes	Yes	Yes
Reinforcement	No	No	Yes*	No	Yes*	Yes
Cuffs	Yes	Yes	Yes	Yes	Yes	Yes
Gown Color	Blue	Blue	Blue	Blue	Blue	Blue

*Note: Include a reinforced panel on the inside of the gown within the front panel and sleeves from the cuff to the elbow.

Summary of Testing:
The surgical gowns testing includes; biocompatibility, linting and cleanliness - particular matter, tensile strength, flammability and ANSI/AMMI PB70:2003 liquid barrier performance. All results of the testing met acceptable and/or required criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Linda Johnson
Regulatory Affairs Specialist
3M Company Corporation
3M Center, Building 275-5W-06
St Paul, Minnesota 55144-1000

APR 14 2011

Re: K101468
Trade/Device Name: 3M™ Surgical 3M™ Basic Disposable Surgical Gown (REF 7492, 7493 & 7494) 3M™ HP Disposable Surgical Gown (REF 7691C, 7692C, 7693C & 7694C) 3M™ Reinforced Disposable Surgical Gown (REF 7595C, 7596C, 7597C, & 7598C) 3M™ Disposable Surgical Gown (REF 7591C, 7592C, 7593C, & 7594C) 3M™ HP Reinforced Disposable Surgical Gown (REF7695C, 7696C 7697C & 7698C)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FYA
Dated: April 5, 2011
Received: April 6, 2011

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

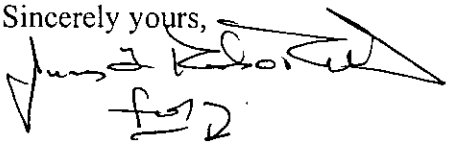
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K101468

Device Name: 3M™ Surgical Gowns

3M™ Basic Disposable Surgical Gown (REF 7492, 7493 & 7494)
3M™ HP Disposable Surgical Gown (REF 7691C, 7692C, 7693C & 7694C)
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These gowns are for single use.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth A. Claverie Wills

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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510(k) Number: K101468